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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,111	09/19/2003	Andrey Yurievich Bogomolov	ACD-002	7653
22832 7590 06/26/2007 Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950			EXAMINER MOSS, KERI A	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 06/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,111	Applicant(s) BOGOMOLOV ET AL.	
	Examiner Keri A. Moss	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/05; 7/12/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims **1-19** are rejected under 35 U.S.C. 102(b) as being anticipated by Vandeginste et al (Multicomponent Self-Modelling Curve Resolution in High-Performance Liquid Chromatography by Iterative Target Transformation Analysis, *Analytica Chimica Acta*, vol 173, pps 253-264 (1985)). Vandeginste teaches a method of characterizing a mixture of components by obtaining a plurality of spectrochromatograms of the mixture of components, each of the spectrochromatograms being obtained under a respective one of a plurality of different chromatographic conditions (paragraph bridging pages 253 and 254); estimating the number of components (paragraph bridging pages 253 and 254), and performing component matching upon the spectrochromatograms using the estimated number of components (Theory section). Additional steps include determining each component retention time in response to the component matching; determining each component spectral shape in response to the component matching; using the component spectral shape to identify the component and resolving at least one component in the mixture of components (Experimental Section). Vandeginste also teaches a method of component peak matching comprising the steps of: obtaining a plurality of spectrochromatographic

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data sets for a mixture of components, each spectrochromatographic data set comprising spectrochromatographic data; creating an augmented spectrochromatographic data set by merging the spectrochromatographic data sets into a matrix; determining a preliminary estimate of the number of components (n) in the augmented spectrochromatographic data set; selecting the (n) most orthogonal spectrochromatographic data from the augmented spectrochromatographic data set; generating a refined key spectra set; and determining the component retention times (Results and Discussion Section). Additional steps include validating each of the (n) most orthogonal spectrochromatographic data using target factor analysis to generate the refined key spectra set (Theory Section), detecting missing components using target testing of each spectrochromatographic data in the refined key spectra set against each of the plurality of spectrochromatographic data sets (Results and Discussion Section); determining a preliminary estimate uses principle component analysis (paragraph bridging pages 253 and 254); determining a preliminary estimate uses single value decomposition (paragraph bridging pages 253 and 254); determining a preliminary estimate uses nonlinear iterative partial least squares (page 254); selecting the (n) most orthogonal spectra uses modified Iterative Key Set Factor Analysis (Results and Discussion); determining the component retention times comprises: performing a regression using the refined key spectra set and the augmented data matrix; and determining retention times as maximum values (Theory). Vandeginste further discloses a method for resolving a mixed sample of chromatographic components, the method comprising the steps of: selecting a plurality of differing chromatographic

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conditions; performing a plurality of chromatographic runs on the mixed sample, each respective run performed under a respective chromatographic condition; obtaining spectrochromatographic data for the mixed sample during each of the chromatographic runs; creating an augmented data set from the spectrochromatographic data of the plurality of chromatographic runs; operating on the augmented data set to determine the retention times for each component in the mixed sample; and resolving each of the components (Experimental Section). Additional steps may be performing component quantitation; performing component quantitation uses resolved spectra and concentration profiles; and finding peak relative areas using concentration profiles (Results and Discussion). Also taught is a method of obtaining the shape of components from spectrochromatographic data comprising the steps of: determining the number of components (n) and each component's retention time; generating uniqueness vectors as initial estimates of spectrochromatographic profiles; and performing profile resolution on the spectrochromatographic data; wherein the step of performing profile resolution uses ALS MCR (Results and Discussion).

3. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamilton et al (Mixture Analysis Using Factor Analysis II: Self-Modeling Curve Resolution, Journal of Chemometrics, vol. 4, pps 1-13 (1990)). Hamilton teaches a method of characterizing a mixture of components by obtaining a plurality of spectrochromatograms of the mixture of components, each of the spectrochromatograms being obtained under a respective one of a plurality of different

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chromatographic conditions; estimating the number of components, and performing component matching upon the spectrochromatograms using the estimated number of components (Section 4. Isolation of Pure Component Spectra from Mixtures).

Additional steps include determining each component retention time in response to the component matching; determining each component spectral shape in response to the component matching; using the component spectral shape to identify the component and resolving at least one component in the mixture of components (Section 6. Other Methods). Hamilton also teaches a method of component peak matching comprising the steps of: obtaining a plurality of spectrochromatographic data sets for a mixture of components, each spectrochromatographic data set comprising spectrochromatographic data; creating an augmented spectrochromatographic data set by merging the spectrochromatographic data sets into a matrix; determining a preliminary estimate of the number of components (n) in the augmented spectrochromatographic data set; selecting the (n) most orthogonal spectrochromatographic data from the augmented spectrochromatographic data set; generating a refined key spectra set; and determining the component retention times (5. Evolving Factor Analysis). Additional steps include validating each of the (n) most orthogonal spectrochromatographic data using target factor analysis to generate the refined key spectra set, detecting missing components using target testing of each spectrochromatographic data in the refined key spectra set against each of the plurality of spectrochromatographic data sets; determining a preliminary estimate uses principle component analysis; determining a preliminary estimate uses single value

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decomposition; determining a preliminary estimate uses nonlinear iterative partial least squares; selecting the (n) most orthogonal spectra uses modified Iterative Key Set Factor Analysis; determining the component retention times comprises: performing a regression using the refined key spectra set and the augmented data matrix; and determining retention times as maximum values (Section 6. Other Methods). Hamilton further discloses a method for resolving a mixed sample of chromatographic components, the method comprising the steps of: selecting a plurality of differing chromatographic conditions; performing a plurality of chromatographic runs on the mixed sample, each respective run performed under a respective chromatographic condition; obtaining spectrochromatographic data for the mixed sample during each of the chromatographic runs; creating an augmented data set from the spectrochromatographic data of the plurality of chromatographic runs; operating on the augmented data set to determine the retention times for each component in the mixed sample; and resolving each of the components (Other Methods). Additional steps may be performing component quantitation; performing component quantitation uses resolved spectra and concentration profiles; and finding peak relative areas using concentration profiles (3. Techniques for Modeling Concentration Profiles).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1743

KAM 6/21/07



BRIAN R. GORDON
PRIMARY EXAMINER